



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

FROM: Deanna Scher, Chemical Review Manager
Reregistration Branch I
Special Review and Reregistration Division (7508C)

TO: OPP Public Docket

SUBJECT: Meeting with BASF to Discuss Vinclozolin Risk Issues

The following document summarizes the meeting held on 03/09/00 between EPA staff and BASF to discuss the risk issues in the vinclozolin risk assessments. This meeting took place during the 30-day registrant-only error correction period, prior to the opening of the public docket.

BASF presented their position on several of the methodologies that the Agency used in the risk assessments and provided suggestions on ways they felt the risk assessments could be further refined. BASF's major talking points are summarized below:

Acute Dietary Risk Assessment: BASF contends that the Agency should regulate at the 99.5th percentile of exposure since field trial data, rather than monitoring data were used in the assessment. They also noted that a concentration factor established from a juicing study should be used when calculating residues in wine. Lastly, BASF provided the Agency with new marketing data which indicate that less than 1% of the grapes in Europe are treated with vinclozolin.

Monitoring Data: BASF undertook a statistical assessment of available analytical data in an effort to establish a defensible index for converting "parent only" crop residue monitoring results into estimates of total residues present. The purpose of the assessment was to allow incorporation of adjusted monitoring data, rather than field trial data, into dietary exposure assessments for vinclozolin.

Cancer Risk Assessment: BASF believes it is inappropriate to regulate vinclozolin using the Q* approach for calculating oncogenic risk. BASF feels that the appropriate method of risk quantification is on a non-linear model - the MOE approach.

Water Exposure Values: BASF believes that the Agency should use the average use pattern (2 applications at 0.5 pounds active ingredient per acre) rather than the maximum use pattern (5 applications at 1 pound) as inputs in the two water exposure models.

Ecological Risk Assessment: BASF believes that EEC values should be estimated using the average use pattern rather than the maximum labeled rate and average values from the Kenaga nomogram.

Risk Mitigation: BASF stated that they are willing to initiate specific label amendments to mitigate unacceptable handler risk and risk to children playing on treated sod.

No decisions were made at the meeting. The Agency encouraged BASF to submit their comments in writing to the docket. Any changes to the risk assessments will be made before the risk assessment is released for public comment and will be available in the docket and on the OPP website, along with BASF's formal comments and the Agency's response to comments.